

## § 874.3930

open or by gently pressing on the columella.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[64 FR 10949, Mar. 8, 1999]

## § 874.3930 Tympanostomy tube with semipermeable membrane.

(a) *Identification*. A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

(b) *Classification*. Class II. The special control for this device is FDA's "Tympanostomy Tubes, Submission Guidance for a 510(k)."

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 17145, Mar. 31, 2000]

## Subpart E—Surgical Devices

### § 874.4100 Epistaxis balloon.

(a) *Identification*. An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

### § 874.4140 Ear, nose, and throat bur.

(a) *Identification*. An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose, or throat area.

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The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]

### § 874.4175 Nasopharyngeal catheter.

(a) *Identification*. A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]

### § 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.

(a) *Identification*. An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (§ 874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

(b) *Classification*. Class II.

### § 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(a) *Identification*. An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass or plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.